

K011041

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JUL - 3 2001

**510(k) Summary of Safety
and Effectiveness Information**

**Regulatory
Authority:**

Safe Medical Devices Act of 1990,
21 CFR 807.92

Company:

BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, CA 92673

Contact:

Ms. Ioana M. RizoIU
BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, CA 92673
(949) 361-1200 (949) 361-0204 Fax

Trade Name:

WaterLase™, Millennium™

Common Name:

Er,Cr:YSGG laser

Classification Name:

Surgical laser instrument

Classification Code:

79 GEX

Equivalent Devices:

BioLase Technology, Inc.

*Elmer™
Twilite™*

Fotona

Fidelis™

Premier Laser Systems

Centauri™

American Dental Technologies

Pulse Master™

Device Description:

The *WaterLase™* dental laser system may be used to perform several dental applications. *WaterLase™* uses advanced laser and water spray technologies to incise, excise and ablate intraoral soft tissues, and cut and remove hard tissues. The Erbium Chromium: Yttrium Scandium Gallium Garnet (Er,Cr:YSGG) solid state laser provides optical energy to oral soft tissues.

A flexible fiberoptic handpiece delivers the *WaterLase™* laser energy. A visible light emitted from the handpiece distal end pinpoints the area of treatment. The optical power output, pulse energy and pulse repetition rate may be adjusted to

specific user requirements. In soft tissue procedures, water spray is applied for hydration, cooling and keeping the tissue clean.

Please refer to the User Manual, section 'Clinical Applications', for detailed instructions on how to use the WaterLase device.

Indications for Use:

Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscesses
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty

Cautions and Contraindications:

All clinical procedures performed with *WaterLase™* must be subjected to the same clinical judgement and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea or an immune system deficiency. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

Substantial Equivalence:

There are no unique applications, indications, materials or specifications presented herein. For all the soft tissue indications for use, **WaterLase™** is substantially equivalent to several erbium laser systems and diode laser systems cleared by the FDA. Equivalent devices include: BioLase Technology, **Elmer™** (K952118, for dental soft tissues); Premier, **Centauri™** (K983211, for oral soft tissues); Fotona, **Fidelis™** (K001527, for oral soft tissues); BioLase Technology, **Twilite™** (K991994, for oral soft tissues including sulcular debridement); and American Dental Technologies, **Pulse Master™** (K961269, K972325, for oral soft tissues, including sulcular debridement).

Conclusion:

WaterLase™ is substantially equivalent to several available, established dental laser products. **WaterLase™** performs through the same mechanism as other laser technologies.

- Evidence of equivalence has been demonstrated through:
 - Equivalent performance specifications
 - Promotional materials for equivalent systems
 - Equivalent intended uses



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL - 3 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Ioana M. Rizoiu
Vice President, Clinical Research
and Development
BioLase Technology, Inc.
981 Calle Amanecer
San Clemente, California 92673

Re: K011041
Trade/Device Name: WaterLase™ Millenium™
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: April 3, 2001
Received: April 5, 2001

Dear Ms. Rizoiu:

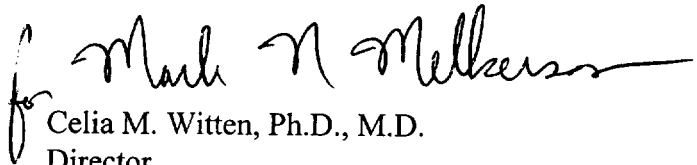
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): *K 011041*

Device Name: **WaterLase™ Millennium™**

Indications for Use:

Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscesses
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)
- Treatment of canker sores, herpetic and apthous ulcers of the oral mucosa
- Vestibuloplasty

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

or

Over-The-Counter-Use

for Mark A. Mathers
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number *K 011041*